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(71) Applicant (for all designated States except US): GUM-LINK A/S [DK/DK]; Dandyvej 19, DK-7100 Vejle (DK).

(72) Inventors; and

(75) Inventors/Applicants (for US only): THORENGAARD, Bitten [DK/DK]; Prangerager 55, DK-7120 Vejle Øst (DK). BOESEN, Dorthe, Schackinger [DK/DK]; Stampesvej 34, DK-7100 Vejle (DK). NISSEN, Vibeke [DK/DK]; Druehaven 45, Taulov, DK-7000 Fredericia (DK).

(74) Agent: PATENTGRUPPEN ApS; Arosgården, Åboulevarden 31, DK-8000 Aarhus C (DK).

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(54) Title: COMPRESSED RESIN MODERATED CHEWING GUM

(57) Abstract: The invention relates to a compressed chewing gum tablet and gum base granule for such tablet comprising at least one elastomer in an amount of about 0% to about 35% by weight of the gum base, at least two resins in an amount of about 15% to about 60% by weight of the gum base, gum base ingredients and where said at least two resins comprising- natural resin in an amount of about 5% to about 40% by weight of the gum base; -synthetic resin in amount of about 10% to about 40% by weight of the gum base

#### Compressed resin moderated chewing gum

#### Field of the invention

The present invention relates to chewing gum granules and chewing gum made on the basis of such chewing gum granules.

#### Background of the invention

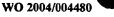
Several different processes for manufacturing of chewing gum are known within the art. The different processes may be overall categorized in basically two different processes; that is chewing gum mechanically mixed on the basis of a gum base compounds or chewing gum compressed on the basis of more or less discrete gum base particles. The first type of chewing gum generally benefits from a very comfortable texture, among several different parameters, most likely due to the mechanically mixing of the polymers and for example the flavors. One disadvantage of such type of process and chewing gum is, however, that the different ingredients, such as encapsulated flavor, active ingredients, etc. may be more or less destroyed or degraded by the mixing process.

The second type of chewing gum generally benefits from a relatively gentle handling of vulnerable additives, such as the above-mentioned flavors or active ingredients. One disadvantage of such type of chewing gum is, however, that the resulting chewing gum tablet may typically disintegrate too easy, especially during the initial chew of the gum.

Different proposals in order to obtain compressed chewing gum have been made in the prior art. Typically, such techniques are directed to adaptation of the manufacturing process. WO 03/011045 discloses a technique where the sticking or adhering of the chewing gum mixture to the tableting process equipment is dealt with by controlling the size of the mixture granules.

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It is one object of the invention to provide a chewing gum compression chewing gum composition, which, when processed by means of compression, provides a texture like conventionally mixed chewing gum.

#### 5 Summary of the invention

The invention relates to a gum base granule comprising

- -at least one elastomer in an amount of about 3% to about 35% by weight of the gum base,
- -at least two resins in an amount of about 15% to about 60% by weight of the gum 10 base,
  - -gum base ingredients, and where said at least two resins comprise
    - -natural resin in an amount of about 5% to about 40% by weight of the gum base
    - -synthetic resin in an amount of about 10% to about 40% by weight of the gum base.

According to the invention, a granule is understood as a small particle whole or completely formed by gum base or derivatives thereof. Typically, granules in large numbers form a granule mixture, made by granulation e.g. by known processes of a gum base "raw material". The gum base granule mixture may typically directly or after pre-processing be compressed to form a tableted (also referred to as a compressed) chewing gum.

According to the invention, the presence of natural resins ensures several important features when dealing with granule mixtures for chewing gum, such as improved stickiness of the final chewing gum tablet, improved robustness to softeners, flavors or other relevant chewing gum additives. On the other hand the balancing between the synthetic and the natural resins ensures that the available gum base may in fact be granulated e.g. by milling without or with reduced risk of sticking to processing equipment. Moreover, a simplified process may be obtained due to the fact that milling of the gum base granules may optionally be completely avoided e.g. by applying a high-speed mixer, e.g. a Lipp Mixer,



According to the invention, the choice of elastomer plasticizers, i.e. natural or synthetic resins, will vary depending on the specific application, and on the type of elastomer(s) being used.

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In an embodiment of the invention, said natural resin comprises one or more different natural resins.

According to an embodiment of the invention, the nature of the different natural resins may typically vary e.g. with respect molecular weight, molecular structure 10 and/or origin.

In an embodiment of the invention, said synthetic resin comprises one or more different synthetic resins.

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According to an embodiment of the invention, the nature of the different synthetic resins may typically vary e.g. with respect to molecular weight. Thus, a combination of for example a low molecular weight and a high molecular weight synthetic resin, e.g. PVA is typically preferred as the synthetic resin forming part of the gum base formulation.

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In an embodiment of the invention, the ratio between the synthetic resin and the natural resin is from about 0.5 to about 7, preferably from about 0.9 to about 6.0.

- 25 According to an embodiment of the invention, a natural resin should always be moderated by synthetic resin, so that the amount of synthetic resin is always at least half the amount of the natural resin present in the gum base and at most in an amount of not more than seven times the amount of natural resins.
- 30 In an embodiment of the invention, the ratio between the synthetic resin and the natural resin is from about 0.9 to about 2.0, preferably from about 0.9 to about 1.5.

According to an embodiment of the invention, a natural resin should always be moderated by synthetic resin, so that the amount of synthetic resin is always at least about 0.9 of the amount of the natural resin present in the gum base and not more than two times the amount of natural resin in the gum base.

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According to a preferred embodiment of the invention, the natural resin should, when applied in relatively large amounts, e.g. about 15 to 35% of the gum base be counteracted or supplemented by an about one-to-one relationship with the synthetic resin of the gum base.

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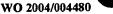
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In an embodiment of the invention, said natural resin comprises rosin esters.

In an embodiment of the invention, said natural resin comprises terpene resins, e.g. derived from alpha-pinene, beta-pinene, and/or d-limonene, natural terpene resins, glycerol esters of gum rosins, tall oil rosins, wood rosins or other derivatives thereof such as glycerol esters of partially hydrogenated rosins, glycerol esters of polymerized rosins, glycerol esters of partially dimerised rosins, pentaerythritol esters of partially hydrogenated rosins, methyl esters of rosins, partially hydrogenated methyl esters of rosins or pentaerythritol esters of rosins and combinations thereof.

In an embodiment of the invention, said synthetic resin comprises polyvinyl acetate, vinyl acetate-vinyl laurate copolymers and mixtures thereof.

- According to an embodiment of the invention, polyvinyl acetate (PVA) may for example have a GPC average molecular weight in the range of 1,000 to about 90,000, such as the range of 3,000 to 80,000 Mn including the range of 30,000 to 50,000.
- According to an embodiment of the invention, the vinyl acetate-vinyl laurate copolymers, e.g. having a vinyl laurate content of about 5 to about 50% by weight, such as 10 to 45% by weight of the copolymer.



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In an embodiment of the invention, said granulated gum base comprising at least one high molecular weight elastomer in an amount of about 0% to about 15% by weight of said gum base, preferably in an amount of about 3% to about 15% by weight of said gum base.

In an embodiment of the invention, the molecular weight of said at least one high molecular weight elastomer is from about 50000 g/mol to 800000 g/mol Mn.

In an embodiment of the invention, said granulated gum base comprising at least one low molecular weight elastomer is in an amount of about 0% to about 25% by weight of said gum base.

In an embodiment of the invention, the molecular weight of said at least one low molecular weight elastomer is from about 1000 g/mol to 50000 g/mol Mn.

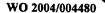
In an embodiment of the invention, said gum base has been added lubricants, antiadherents and glidants such as metallic stearates, hydrogenated vegetable oils, partially hydrogenated vegetable oils, polyethylene glycols, polyoxyethylene monostearates, animal fats, silicates, silicates dioxide, talc, magnesium stearates, calcium stearates, fumed silica, powdered hydrogenated cottonseed oils, hydrogenated vegetable oils, hydrogenated soya oil and mixtures thereof.

According to a preferred embodiment of the invention, the gum base is added lubricants, anti-adherents and glidants in an amount as small as possible thereby avoiding reduced texture properties.

In an embodiment of the invention, the gum base is substantially free of lubricants, anti-adherents and glidants.

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According to a preferred embodiment of the invention, the gum base is substantially free of lubricants, anti-adherents and glidants, thereby obtaining as much texture-





improvement as possible by means of the applied combination of synthetic and natural resins.

In an embodiment of the invention, the natural resins provide an improved and sticky texture of the gum base when applied in chewing gum formulation.

In an embodiment of the invention, said gum base is substantially wax free.

According to an advantageous embodiment of the invention, a substantially wax-free gum base formulation has been obtained having advantageous texture properties when the gum base formulation is moderated with respect to the balance between the synthetic and the natural resins.

In an embodiment of the invention, said gum base is substantially fat free.

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A substantially fat-free chewing gum formulation benefits for example from improved healthiness.

In an embodiment of the invention, the gum base has a water content of less than 20 2.0%, preferably less than 1.5% by weight of the gum base.

In an embodiment of the invention, said gum base comprises filler in an amount of about 0% to about 50% by weight of the gum base.

In an embodiment of the invention, said gum base comprises synthetic resin in an amount of about 15% to about 40% by weight of the gum base.

According to an embodiment of the invention, a relatively high amount of natural resin, e.g. 20% by weight of the gum base, would typically result in a somewhat reduced use of synthetic resin. An example of such an application would be a ratio of about 1-to-1, whereas reduced content of natural resin advantageously may result in an increased ratio.



In an embodiment of the invention, said gum base comprises emulsifiers and/or fats in an amount of about 10% to about 40% by weight of the gum base.

In an embodiment of the invention, said gum base comprises wax in an amount of about 2% to about 30% by weight of the gum base.

In an embodiment of the invention, at least a part of the flavoring agents has been teared into at least a part of the gum base previous to compression.

According to an embodiment of the invention, such tearing or incorporation of flavor into the gum base or at least a part of the gum base may e.g. imply mixing of gum base components mechanically during addition of flavor components.

Moreover, the invention relates to a compressed chewing gum comprising elastomer in the amount of about 0.3% to 32% by weight, preferably about 5% to 25% by weight of the chewing gum,

resin in the amount of about 1.5% to 55% by weight, preferably about 4% to 30% by weight of the chewing gum,

and chewing gum additives, wherein said resin comprises

- -natural resin in the amount of about 0.5% to 35% by weight, preferably about 4% to 30% by weight of the chewing gum,
  -synthetic resin in the amount of about 1% to 35% by weight, preferably about 4% to 30% by weight of the chewing gum,
- According to the invention, the percent by weight measure in relation to the chewing gum refers to the complete chewing gum, except any optional coating.





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According to the invention, a compressed chewing gum has been made by means of compression of gum base granules and chewing gum additives.

According to the invention, the processing abilities of chewing gum base for the purpose of providing a tableted compressed chewing gum is obtained by the providing of a gum base which by nature, i.e. due to the composition, has improved properties with respect to e.g. granulation or other similar pre-processing.

According to the invention it has been realized that natural resins may in fact be used actively for the purpose of moderating the tackiness between two opposing limits, i.e. a lower limit defined by the minimum desired tackiness of the chewing gum and an upper limit defined by the process according to which the chewing gum is made.

Thus, when applying a natural resin in compressed chewing gum, an advantageous initial chew may be obtained. On the other hand, resin tends to complicate the preprocessing of the gum base material due to sticking to the processing equipment, such as granulation equipment, compression equipment, etc.

According to an embodiment of the invention, the desired tackiness may be obtained by applying both natural and synthetic resins in the granulate gum base and by adjusting the mutual balance between the applied amounts of natural and synthetic resins.

In an embodiment of the invention, said chewing gum additives comprises

sweeteners in the amount of about 5 to about 95% by weight of the chewing gum,
more typically about 20 to about 80% by weight, such as 30 to 60% by weight of the
chewing gum.

In an embodiment of the invention, the compressed chewing gum tablet comprises about 0.1% to 15% by weight of flavoring agents, preferably about 0.8% to 5% by weight.







In an embodiment of the invention, said natural resin comprises one or more different natural resins.

According to an embodiment of the invention, the nature of the different natural resins may typically vary e.g. with respect to molecular weight, molecular structure and/or origin.

In an embodiment of the invention, said synthetic resin comprises one or more different synthetic resins.

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According to an embodiment of the invention, the nature of the different synthetic resins may typically vary e.g. with respect to molecular weight. Thus, a combination of for example a low molecular weight and a high molecular weight synthetic resin, e.g. PVA is typically preferred as the synthetic resin forming part of the gum base formulation.

In an embodiment of the invention, the ratio between the synthetic resin and the natural resin is from about 0.5 to about 7, preferably from about 0.9 to about 6.0.

- According to an embodiment of the invention, a natural resin should always be moderated by synthetic resin, so that the amount of synthetic resin is always at least half the amount of the natural resin present in the gum base and at most in an amount of not more than seven times the amount of natural resins.
- In an embodiment of the invention the ratio between the synthetic resin and the natural resin is from about 0.9 to about 2.0, preferably from about 0.9 to about 1.5.

According to an embodiment of the invention, a natural resin should always be moderated by synthetic resin, so that the amount of synthetic resin is always at least about 0.9 of the amount of the natural resin present in the gum base and not more than two times the amount of natural resins in the gum base.



According to a preferred embodiment of the invention, the natural resin should, when applied in relatively large amounts, e.g. about 15 to 35% of the gum base, be counteracted or supplemented by an about one-to-one relationship with the synthetic resins of the gum base.

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In an embodiment of the invention, said natural resin comprises rosin esters.

In an embodiment of the invention, said natural resin comprises terpene resins, e.g. derived from alpha-pinene, beta-pinene, and/or d-limonene, natural terpene resins, glycerol esters of gum rosins, tall oil rosins, wood rosins or other derivatives thereof such as glycerol esters of partially hydrogenated rosins, glycerol esters of polymerized rosins, glycerol esters of partially dimerised rosins, pentaerythritol esters of partially hydrogenated rosins, methyl esters of rosins, partially hydrogenated methyl esters of rosins or pentaerythritol esters of rosins and combinations thereof.

In an embodiment of the invention, said synthetic resin comprises polyvinyl acetate, vinyl acetate-vinyl laurate copolymers and mixtures thereof.

- According to an embodiment of the invention polyvinyl acetate (PVA) may for example have a GPC average molecular weight in the range of 1,000 to about 90,000, such as the range of 3,000 to 80,000 Mn including the range of 30,000 to 50,000.
- According to an embodiment of the invention, the vinyl acetate-vinyl laurate copolymers, e.g. having a vinyl laurate content of about 5 to about 50% by weight, such as 10 to 45% by weight of the copolymer.
- In an embodiment of the invention, said chewing gum comprising at least one high molecular weight elastomer in an amount of about 0% to about 14% by weight of said chewing gum, preferably about 0.5% to about 10% by weight of said chewing gum.



In an embodiment of the invention, the molecular weight of said at least one high molecular weight elastomer is from about 50000 g/mol to 800000 g/mol Mn.

In an embodiment of the invention, said chewing gum comprising at least one low molecular weight elastomer is in an amount of about 0% to about 20% by weight of said chewing gum.

In an embodiment of the invention, the molecular weight of said at least one low molecular weight elastomer is from about 1000 g/mol to 50000 g/mol Mn.

In an embodiment of the invention, said chewing gum comprises lubricants, antiadherents and glidants such as metallic stearates, hydrogenated vegetable oils, partially hydrogenated vegetable oils, polyethylene glycols, polyoxyethylene monostearates, animal fats, silicates, silicates dioxide, talc, magnesium stearates, calcium stearates, fumed silica, powdered hydrogenated cottonseed oils, hydrogenated vegetable oils, hydrogenated soya oil and mixtures thereof.

According to a preferred embodiment of the invention, the chewing gum comprises
lubricants, anti-adherents and glidants in an amount as small as possible thereby
avoiding reduced texture properties.

In an embodiment of the invention the chewing gum is substantially free of lubricants, anti-adherents and glidants.

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According to a preferred embodiment of the invention, the chewing gum is substantially free of lubricants, anti-adherents and glidants, thereby obtaining as much texture-improvement as possible by means of the applied combination of synthetic and natural resins.

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In an embodiment of the invention, the natural resins provide an improved and sticky texture of the chewing gum when applied in chewing gum formulation.

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In an embodiment of the invention, said chewing gum is substantially wax free.

According to an advantageous embodiment of the invention, a substantially wax-free chewing gum formulation has been obtained having advantageous texture properties when the chewing gum formulation is moderated with respect to the balance between the synthetic and the natural resins.

In an embodiment of the invention, said chewing gum is substantially fat free.

A substantially fat-free chewing gum formulation benefits for example from improved healthiness.

In an embodiment of the invention, the chewing gum has a water content of less than 2.0%, preferably less than 1.5% by weight of the chewing gum.

In an embodiment of the invention, said chewing gum comprises filler in an amount of about 0% to about 50% by weight of the chewing gum.

In an embodiment of the invention, said chewing gum comprises synthetic resin in an amount of about 1.5% to about 35% by weight of the chewing gum.

According to an embodiment of the invention, a relatively high amount of natural resin, e.g. 20% by weight of the gum base, would typically result in a somewhat reduced use of synthetic resin. An example of such an application would be a ratio of about 1-to-1, whereas reduced content of natural resin advantageously may result in an increased ratio.

In an embodiment of the invention, said chewing gum comprises emulsifiers and/or fats in an amount of about 0.1% to about 35% by weight of the chewing gum.

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In an embodiment of the invention, said chewing gum comprises wax in an amount of about 0.5 to about 30% by weight of the chewing gum.

In an embodiment of the invention, at least a part of the flavoring agents has been teared into the chewing gum forming gum base granules or part of the gum base granules previous to compression.

In an embodiment of the invention, said chewing gum additives comprise active ingredients.

In an embodiment of the invention, at least a part of said active ingredients has been teared into the chewing gum or at least a part of the chewing gum previous to compression.

Moreover, the invention relates to a compressed chewing gum tablet comprising gum base according to any of the claims 1-24 in an amount of about 10% to 90% by weight of the chewing gum tablet.

The invention also facilitates the providing of a compressed chewing gum tablet comprising a chewing gum center fully or partly encapsulated by a barrier layer, said gum center comprising a compression of gum base granules and chewing gum additives, said gum base granules having a moderated tackiness.

Gum base additives may, according to the invention, broadly refer to sweeteners,
25 flavors, acids, colors, active ingredients, cooling agents, freeze-dried fruit, etc.
Moreover, the applied ingredients may be encapsulated.

Moreover, according to the invention, it has been recognized that controlling of tackiness, preferably established by means of natural resins facilitates a more freely selected group of tablet shapes.





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According to the invention, it is now possible to obtain a chewing gum tablet, made by means of compression of a gum base granulate and chewing gum additives, having an acceptable and improved immediate initial texture.

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According to the invention, it is possible to obtain the desired texture by means of natural resins mixed into the gum base previous to the compression of gum base granulates.

It should be noted that although natural resins are preferred for the adjustment of the desired texture, synthetic resin may be added to the gum base or the chewing gum, if so desired.

Evidently, according to the invention, further additives may be added to the gum base, e.g. during mixing or after mixing.

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Moreover, according to the invention, it has been recognized that the natural resin facilitates an advantageous overall flavor release when the compressed chewing gum tablet is chewed. This may partly be due to the fact that the initial chewing of the gum tablet results in an immediate release of flavor particles and at the same time that a part of the dissolved flavor particles reacts or become incorporated into the chewing gum base.

The last part of the flavor release results in prolonging of the overall flavor release time.

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According to conventional chewing gum manufacturing several efforts have been made in making chewing gum less sticky.

Moreover, a further advantage of the chewing gum tablet according to the invention is that the tablet may be handled and temporarily stored prior to the final processing such as coating and the final packaging.

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The upper limit of the desired tackiness is reached, when the gum base granules can no longer be processed by conventional compression techniques.

Generally, the above mentioned advantages may be summed up to be that stickiness may actually be obtained in chewing gums made by compression and not only by the traditional mixing methods.

Moreover, according to the invention, it has been recognized that the natural resin facilitates an advantageous overall flavor release when the compressed chewing gum tablet is chewed. This may partly be due to the fact that the initial chewing of the gum tablet results in an immediate release of distinct flavor particle and at the same time, that a part of the dissolved flavor particles reacts or become incorporated into the chewing gum base. On the other hand, the natural resins as provided and balanced with respect synthetic resins according to the invention has shown advantageous release properties compared to e.g. chewing gums comprising synthetic resins only.

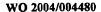
When the moderated tackiness is obtained by means of at least one natural resin incorporated in at least a part of the gum base granules, a further advantageous embodiment of the invention has been obtained.

According to the invention, the "% by weight" of the chewing gum tablet refers to the un-coated chewing gum tablet.

When the compressed chewing gum tablet comprises about 0.1% to 15% by weight of flavoring agents, preferably about 0.8% to 5% by weight, a further advantageous embodiment of the invention has been obtained.

The amount of flavor depends heavily of the applied type of flavor and whether the flavor has been partly teared into the gum base or part of the gum base previous to the compression of the gum base granules and the chewing gum additives.





When the natural resins provide an improved and sticky texture of the tablet, a further advantageous embodiment of the invention has been obtained.

According to the invention, natural resins provide an improved and sticky texture of the final compressed tablet compared to traditional compressed chewing gum.

When the gum center comprises wax, a further advantageous embodiment of the invention has been obtained.

- The desired moderated tackiness may in certain compositions be "tuned" by means of the wax content, which, when applied in an increased amount in the context of certain gum base compounds, may increase the tackiness of the final barrier-encapsulated composition.
- When the gum center is substantially free of wax, a further advantageous embodiment of the invention has been obtained.

According to an embodiment of the invention, adjustment of the desired initial tackiness may be performed without wax.

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When the gum base granules comprise pre-mixed active ingredients, a controlled release of active ingredients may be obtained by means of at least a double active ingredients buffer, the first buffer comprising active ingredients blended into the final mix immediately prior to compression, the second buffer comprising active ingredients blended into the gum base prior to the blending of gum base and chewing gum base additives.

In this way, the balance between pre-mixed ingredients and normal compressed ingredients, a certain desired balance between early and late release of active ingredients may be obtained.

### Figures

The invention will be described in the following with reference to the figures in which

5	fig. 1	illustrates a chewing gum tablet according to the invention,
	fig. 2a and 2b	illustrate flowcharts of two applicable alternative manufacturing
	J	methods according to examples of embodiments of the invention,
	fig. 3	illustrates the compression of a chewing gum according to one
	J	embodiment of the invention, and where
10	fig. 4	illustrates the compression of a chewing gum according to another
		embodiment of the invention.

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#### **Detailed description**

Fig. 1 illustrates a chewing gum tablet according to the invention.

The fig. 1 illustrates a chewing gum tablet made on the basis of compressed gum base granulates. The gum tablet comprises a barrier layer 1 encapsulating or partly encapsulating a gum base center 2.

The gum base granulates are made on the basis of a gum base. As used herein, the expression "gum base" refers in general to the water insoluble part of the chewing gum, which typically constitutes 10 to 90% by weight including the range of 15-50% by weight of the total chewing gum formulation. Chewing gum base formulations typically comprise one or more elastomeric compounds of synthetic or natural origin, at least two resinous compounds which, according to the invention is both of synthetic or natural origin, fillers, softening compounds and minor amounts of miscellaneous ingredients such as antioxidants and colorants, etc.

According to a preferred embodiment of the invention, the gum base should always comprise at least an amount of 5% by weight of natural resins and less than about 40% by weight of the gum base and the synthetic resin should be present in an amount of about 15% to about 40% by weight of the gum base.

The composition of chewing gum base formulations mixed with chewing gum additives, as defined below can vary substantially depending on the particular product to be prepared and on the desired masticatory and other sensory characteristics of the final product. However, typical ranges (weight%) of the above gum base components are: 5 to 50% by weight elastomeric compounds, 5 to 55% by weight resins, 0 to 50% by weight filler/texturiser, 5 to 35% by weight softener and 0 to 1% by weight of miscellaneous ingredients such as antioxidants, colorants, etc.

The barrier layer 1 may preferably be applied during or prior to the processing of the tablet.

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The barrier layer, e.g. Mg Stearate, forms an outer barrier of the gum tablet.

Further layers may be applied to the tablet, such as traditional coatings.

Fig. 2a shows a typical flowchart, illustrating the major steps of one of several applicable manufacturing processes within the scope of the invention.

In step 21, a suitable gum base is prepared according to the prescriptions of the invention.

According to a preferred embodiment of the invention, the gum base is partly premixed with a moderated amount of flavor and/or active ingredients.

The pre-mixing of flavors or active ingredients may e.g. be performed by means of conventional mixers, e.g. a Z-blade mixer, during no or preferably relatively little added heating and substantially under atmospheric pressure. Preferably, the pre-mixing (also referred to a tearing) should be purely mechanically and should be performed sufficiently enough to result in a homogeneous blend of the flavor and/or active ingredients into the gum base.

Typical duration in time of mixing may be between few minutes op to e.g. 30 minutes. Evidently, according to the invention, other temperatures, pressures, duration in time and mixing methods may be applied for the purpose of mixing active ingredients and/or flavors into the gum base and thereby the gum base granulate applied for the subsequent compression.

In step 22, the provided gum base is grinding (by some referred to as granulated). The granulating may be performed by means of well-known techniques. One of those techniques implies an initial cooling of the gum base immediately prior to granulation. If the consistence of the gum base allows so, the provided gum base may be granulated at room temperature.

According to an advantageous embodiment of the invention, bulk-sweeteners may advantageously be applied as a grinding aid. Sorbitol can be used as a non-sugar sweetener. Other useful non-sugar sweeteners include, but are not limited to, other sugar alcohols such as mannitol, xylitol, hydrogenated starch hydrolysates, maltitol, isomaltol, erythritol, lactitol and the like, alone or in combination.

In step 23, the gum base granulate is blended with suitable chewing gum additives.

In the present context, chewing gum additives include bulk sweeteners, high-10 intensity sweeteners, flavoring agents, softeners, emulsifiers, coloring agents, binding agents, acidulants, fillers, antioxidants and other components such as pharmaceutically or biologically active substances, that confer desired properties to the finished chewing gum product.

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Examples of suitable sweeteners are listed below.

Suitable bulk sweeteners include e.g. both sugar and non-sugar components. Bulk sweeteners typically constitute from about 5 to about 95% by weight of the chewing gum, more typically about 20 to about 80% by weight such as 30 to 60% by weight of the gum.

Useful sugar sweeteners are saccharide-containing components commonly known in the chewing gum art including, but not limited to, sucrose, dextrose, maltose, dextrins, trehalose, D-tagatose, dried invert sugar, fructose, levulose, galactose, corn

syrup solids, and the like, alone or in combination.

Sorbitol can be used as a non-sugar sweetener. Other useful non-sugar sweeteners include, but are not limited to, other sugar alcohols such as mannitol, xylitol,

hydrogenated starch hydrolysates, maltitol, isomaltol, erythritol, lactitol and the like, 30 alone or in combination.

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High-intensity artificial sweetening agents can also be used alone or in combination with the above sweeteners. Preferred high-intensity sweeteners include, but are not limited to, sucralose, aspartame, salts of acesulfame, alitame, saccharin and its salts, neotam, cyclamic acid and its salts, glycyrrhizin, dihydrochalcones, thaumatin, monellin, sterioside and the like, alone or in combination. In order to provide longer lasting sweetness and flavor perception, it may be desirable to encapsulate or otherwise control the release of at least a portion of the artificial sweetener. Techniques such as wet granulation, wax granulation, spray drying, spray chilling, fluid bed coating, coascervation, encapsulation in yeast cells and fiber extrusion may be used to achieve desired release characteristics. 10

Usage level of the artificial sweetener will vary considerably depending e.g. on factors such as potency of the sweetener, rate of release, desired sweetness of the product, level and type of flavor used and cost considerations. Thus, the active level of artificial sweetener may vary from about 0.02 to about 8% by weight. When carriers used for encapsulation are included, the usage level of the encapsulated sweetener will be proportionately higher. Combinations of sugar and/or non-sugar sweeteners can be used in the chewing gum formulation processed in accordance with the invention. Additionally, the softener may also provide additional sweetness such as with aqueous sugar or alditol solutions.

If a low-calorie gum is desired, a low-calorie bulking agent can be used. Examples of low-calorie bulking agents include polydextrose, Raftilose, Raftilin, Inuline, fructooligosaccharides (NutraFlora®), palatinose oligosaccharided; guar gum hydrolysates (e.g. Sun Fiber®) or indigestible dextrins (e.g. Fibersol®). However, other low-calorie bulking agents can be used.

Further chewing gum additives, which may be included in the chewing gum mixture processed in the present process include surfactants and/or solubilisers, especially when pharmaceutically, cosmetically or biologically active ingredients are present. As examples of types of surfactants to be used as solubilisers in a chewing gum composition according to the invention reference is made to H.P. Fiedler, Lexikon

der Hilfstoffe für Pharmacie, Kosmetik und Angrenzende Gebiete, page 63-64 (1981) and the lists of approved food emulsifiers of the individual countries. Anionic, cationic, amphoteric or non-ionic solubilisers can be used. Suitable solubilisers include lecithins, polyoxyethylene stearate, polyoxyethylene sorbitan fatty acid esters, fatty acid salts, mono and diacetyl tartaric acid esters of mono and diglycerides of edible fatty acids, citric acid esters of mono and diglycerides of edible fatty acids, saccharose esters of fatty acids, polyglycerol esters of fatty acids, polyglycerol esters of interesterified castor oil acid (E476), sodium stearoyllatylate, sodium lauryl sulfate and sorbitan esters of fatty acids and polyoxyethylated hydrogenated castor oil (e.g. the product sold under the trade name CREMOPHOR), 10 block copolymers of ethylene oxide and propylene oxide (e.g. products sold under trade names PLURONIC and POLOXAMER), polyoxyethylene fatty alcohol ethers, polyoxyethylene sorbitan fatty acid esters, sorbitan esters of fatty acids and polyoxyethylene steraric acid esters.

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Particularly suitable solubilisers are polyoxyethylene stearates, such as for instance polyoxyethylene(8)stearate and polyoxyethylene(40)stearate, the polyoxyethylene sorbitan fatty acid esters sold under the trade name TWEEN, for instance TWEEN 20 (monolaurate), TWEEN 80 (monooleate), TWEEN 40 (monopalmitate), TWEEN 60 (monostearate) or TWEEN 65 (tristearate), mono and diacetyl tartaric acid esters of mono and diglycerides of edible fatty acids, citric acid esters of mono and diglycerides of edible fatty acids, sodium stearoyllactylate, sodium laurylsulfate, polyoxyethylated hydrogenated castor oil, blockcopolymers of ethylene oxide and propyleneoxide and polyoxyethylene fatty alcohol ether. The solubiliser may either be a single compound or a combination of several compounds. The expression "solubiliser" is used in the present text to describe both possibilities, the solubiliser used must be suitable for use in food and/or medicine.

In the presence of an active ingredient the chewing gum may preferably also comprise a carrier known in the art.

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One significant advantage of the present process is that the temperature throughout the entire operation can be kept at a relatively low level such as it will be described in the following. This is an advantageous feature with regard to preserving the aroma of added flavoring components, which may be prone to deterioration at higher temperatures. Aroma agents and flavoring agents which are useful in a chewing gum produced by the present process are e.g. natural and synthetic flavorings (including natural flavorings) in the form of freeze-dried natural vegetable components, essential oils, essences, extracts, powders, including acids and other substances capable of affecting the taste profile. Examples of liquid and powdered flavorings include coconut, coffee, chocolate, vanilla, grape fruit, orange, lime, menthol, liquorice, caramel aroma, honey aroma, peanut, walnut, cashew, hazelnut, almonds, pineapple, strawberry, raspberry, tropical fruits, cherries, cinnamon, peppermint, wintergreen, spearmint, eucalyptus, and mint, fruit essence such as from apple, pear, peach, strawberry, apricot, raspberry, cherry, pineapple, and plum essence. The essential oils include peppermint, spearmint, menthol, eucalyptus, clove oil, bay oil, anise, thyme, cedar leaf oil, nutmeg, and oils of the fruits mentioned above.

In one preferred embodiment, the flavor is one or more natural flavoring agent(s) which is/are freeze-dried, preferably in the form of a powder, slices or pieces or combinations thereof. The particle size of such agents may be less than 3 mm, such as less than 2 mm, more preferred less than 1 mm, calculated as the longest dimension of the particle. The natural flavoring agent may also be in a form where the particle size is from about 3  $\mu$ m to 2 mm, such as from 4  $\mu$ m to 1 mm. Preferred natural flavoring agents include seeds from a fruit e.g. from strawberry, blackberry and raspberry.

Various synthetic flavors, such as mixed fruit flavor may also be used according to the present invention. As indicated above, the aroma agent may be used in quantities smaller than those conventionally used. The aroma agents and/or flavors may be used in an amount of about 0.01 to about 30% by weight of the final product depending on the desired intensity of the aroma and/or flavor used. Preferably, the content of aroma/flavor is in the range of about 0.2 to 3% by weight of the total composition.

According to the invention, encapsulated flavors or active ingredients, may be added to the final blend, e.g. in step 23 of fig. 2, prior to compression.

Different methods of encapsulating flavors or active ingredients, which may both refer to flavors or active ingredients mixed into the gum base and flavors or active ingredients compressed into the chewing gum may e.g. include Spray drying, Spray cooling, Film coating, Coascervation, Double emulsion method (Extrusion technology) or Prilling.

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Materials to be used for the above-mentioned encapsulation methods may e.g. include Gelatine, Wheat protein, Soya protein, Sodium caseinate, Caseine, Gum arabic, Mod. starch, Hydrolyzed starches (maltodextrines), Alginates, Pectin, Carregeenan, Xanthan gum, Locus bean gum, Chitosan, Bees wax, Candelilla wax, Carnauba wax, Hydrogenated vegetable oils, Zein and/or Sucrose.

Active ingredients may be added to chewing gum. Preferably, these ingredients should be added subsequent to any significant heating or mixing. In other words, the active ingredients, should preferably be added immediately prior to the compression

20 of the final tablet.

Referring to the process illustrated in fig. 2, the adding of active ingredients may be cautiously blended with pre-mixed gum base granulates and further desired additives, immediately prior to the final compression of the tablet.

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Examples of suitable active ingredients are listed below.

In one embodiment of the invention, the chewing gum comprises a pharmaceutically, cosmetically or biologically active substance. Examples of such active substances, a comprehensive list of which is found e.g. in WO 00/25598, which is incorporated herein by reference, include drugs, dietary supplements, antiseptic agents, pH-adjusting agents, anti-smoking agents and substances for the care or treatment of the

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oral cavity and the teeth such as hydrogen peroxide and compounds capable of releasing urea during chewing. Examples of useful active substances in the form of antiseptics include salts and derivatives of guanidine and biguanidine (for instance chlorhexidine diacetate) and the following types of substances with limited watersolubility: quaternary ammonium compounds (e.g. ceramine, chloroxylenol, crystal violet, chloramine), aldehydes (e.g. paraformaldehyde), derivatives of dequaline, polynoxyline, phenols (e.g. thymol, p-chlorophenol, cresol), hexachlorophene, salicylic anilide compounds, triclosan, halogenes (iodine, iodophores, chloroamine, dichlorocyanuric acid salts), alcohols (3,4 dichlorobenzyl alcohol, benzyl alcohol, phenoxyethanol, phenylethanol), cf. also Martindale, The Extra Pharmacopoeia, 28th edition, page 547-578; metal salts, complexes and compounds with limited watersolubility, such as aluminum salts, (for instance aluminum potassium sulphate AlK(SO<sub>4</sub>)<sub>2</sub>,12H<sub>2</sub>O) and salts, complexes and compounds of boron, barium, strontium, iron, calcium, zinc, (zinc acetate, zinc chloride, zinc gluconate), copper (copper chloride, copper sulphate), lead, silver, magnesium, sodium, potassium, 15 lithium, molybdenum, vanadium should be included; other compositions for the care of mouth and teeth: for instance; salts, complexes and compounds containing fluorine (such as sodium fluoride, sodium monofluorophosphate, aminofluorides, stannous fluoride), phosphates, carbonates and selenium. Further active substances can be found in J. Dent.Res. Vol. 28 No. 2, page 160-171,1949. 20

Examples of active substances in the form of agents adjusting the pH in the oral cavity include: acids, such as adipinic acid, succinic acid, fumaric acid, or salts thereof or salts of citric acid, tartaric acid, malic acid, acetic acid, lactic acid, phosphoric acid and glutaric acid and acceptable bases, such as carbonates, hydrogen carbonates, phosphates, sulphates or oxides of sodium, potassium, ammonium, magnesium or calcium, especially magnesium and calcium.

Active ingredients may comprise the below-mentioned compounds or derivates thereof but are not limited thereto: Acetaminophen, Acetylsalicylsyre Buprenorphine 30 Bromhexin Celcoxib Codeine, Diphenhydramin, Diclofenac, Etoricoxib, Ibuprofen, Indometacin, Ketoprofen, Lumiracoxib, Morphine, Naproxen, Oxycodon, Parecoxib,

Tramadol, Valdecoxib, Tenoxicam, Rofecoxib, Pseudoefedrin, Piroxicam, Calciumcarbonat, Magaldrate, Disulfiram, Bupropion, Nicotine, Azithromycin, Granisetron, Erythromycin, Tetracycline, Clotrimazole, Clarithromycin, Ondansetron, Prometazin, Tropisetron, Brompheniramine, Ceterizin, leco-Ceterizin, Chlorcyclizine, Chlorpheniramin, Chlorpheniramin, Difenhydramine, Doxylamine, 5 Fenofenadin, Guaifenesin, Loratidin, des-Loratidin, Phenyltoloxamine, Promethazin, Pyridamine, Terfenadin, Troxerutin, Methyldopa, Methylphenidate, Benzalcon. Ecabet-sodium, Chlorhexidine, Cetylpyrid. Chloride, Benzeth. Chloride, Haloperidol, Allopurinol, Colchinine, Theophylline, Propanolol, Prednisolone, Prednisone, Fluoride, Urea, Actot, Glibenclamide, Glipizide, Metformin, Miglitol, 10 Sildenafil, Vardenafil, Cialis. Apomorfin, Rosiglitazone, Repaglinide, Simethicone, Cimetidine, Famotidine, Ranitidine, Ratinidine, Diphenoxylate, cetrizin, Loratadine, Aspirin, Benzocaine, Dextrometorphan, Phenylpropanolamine, Metoclopramide, Acyclovir, Domperidone, Cisapride, Pseudoephedrine, Dioctylsulfosucc., Phenolphtalein, Almotriptan, Eletriptan, Ergotamine, Migea, 15 Naratriptan, Rizatriptan, Sumatriptan, Zolmitriptan, Aluminum salts, Calcium salts, Ferro salts, Silver salts, Zinc-salts, Amphotericin B, Chlorhexidine, Miconazole, Triamcinolonacetonid, Melatonine, Phenobarbitol, Caffeine, Benzodiazepiner, Hydroxyzine, Meprobamate, Phenothiazine, Buclizine, Brometazine, Cinnarizine, Cyclizine, Difenhydramine, Dimenhydrinate, Buflomedil, Amphetamine, Caffeine, 20 Ephedrine, Orlistat, Phenylephedrine, Phenylpropanolamin, Pseudoephedrine, Sibutramin, Ketoconazole, Nitroglycerin, Nystatin, Progesterone, Testosterone, Vitamin B12, Vitamin C, Vitamin A, Vitamin D, Vitamin E, Pilocarpin, Aluminiumaminoacetat, Cimetidine, Esomeprazole, Famotidine, Lansoprazole, Magnesiumoxide, Nizatide and or Ratinidine. 25

The invention is suitable for increased or accelerated release of active agents selected among the group of dietary supplements, oral and dental compositions, antiseptic agents, pH-adjusting agents, anti-smoking agents, sweeteners, flavorings, aroma agents or drugs. Some of those will be described below.

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The active agents to be used in connection with the present invention may be any substance desired to be released from the chewing gum. The active agents, for which a controlled and/or accelerated rate of release is desired, are primarily substances with a limited water-solubility, typically below 10 g/100 ml inclusive of substances which are totally water-insoluble. Examples are medicines, dietary supplements, oral compositions, anti-smoking agents, highly potent sweeteners, pH-adjusting agents, flavorings, etc.

Other active ingredients are, for instance, paracetamol, benzocaine, cinnarizine, menthol, carvone, caffeine, chlorhexidine-di-acetate, cyclizine hydrochloride, 1,8cineol, nandrolone, miconazole, mystatine, aspartame, sodium fluoride, nicotine, saccharin, cetylpyridinium chloride, other quaternary ammonium compounds, vitamin E, vitamin A, vitamin D, glibenclamide or derivatives thereof, progesterone, acetylsalicylic acid, dimenhydrinate, cyclizine, metronidazole, sodium hydrogencarbonate, the active components from ginkgo, the active components from propolis, the active 15 components from ginseng, methadone, oil of peppermint, salicylamide, hydrocortisone or astemizole.

Examples of active agents in the form of dietary supplements are for instance salts and compounds having the nutritive effect of vitamin B2 (riboflavin), B12, Folic acid, niacine, biotine, poorly-soluble glycerophosphates, amino acids, the vitamins A, D, E and K, minerals in the form of salts, complexes and compounds containing calcium, phosphorus, magnesium, iron, zinc, copper, iodine, manganese, chromium, selenium, molybdenum, potassium, sodium or cobalt.

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Furthermore, reference is made to lists of nutrients accepted by the authorities in different countries such as for instance US code of Federal Regulations, Title 21, Section 182.5013.182 5997 and 182.8013-182.8997.

Examples of active agents in the form of compounds for the care or treatment of the 30 oral cavity and the teeth, are for instance bound hydrogen peroxide and compounds capable of releasing urea during chewing.

Examples of active agents in the form of antiseptics are for instance salts and compounds of guanidine and biguanidine (for instance chlorhexidine diacetate) and the following types of substances with limited water-solubility: quaternary ammonium compounds (for instance ceramine, chloroxylenol, crystal violet, 5 chloramine), aldehydes (for instance paraformaldehyde), compounds of dequaline, polynoxyline, phenols (for instance thymol, para chlorophenol, cresol) hexachlorophene, salicylic anilide compounds, triclosan, halogenes (iodine, iodophores, chloroamine, dichlorocyanuric acid salts), alcohols (3,4 dichlorobenzyl alcohol, benzyl alcohol, phenoxyethanol, phenylethanol), cf. furthermore Martindale, 10 The Extra Pharmacopoeia, 28th edition, page 547-578; metal salts, complexes and compounds with limited water-solubility, such as aluminum salts, (for instance aluminum potassium sulfate AlK(SO<sub>4</sub>)<sub>2</sub>,12H<sub>2</sub>O) and furthermore salts, complexes and compounds of boron, barium, strontium, iron, calcium, zinc, (zinc acetate, zinc chloride, zinc gluconate), copper (copper chloride, copper sulfate), lead, silver, mag-15 nesium, sodium, potassium, lithium, molybdenum, vanadium should be included; other compositions for the care of mouth and teeth: for instance; salts, complexes and compounds containing fluorine (such as sodium fluoride, sodiummonofluorophosphate, aminofluorides, stannous fluoride), phosphates, carbonates and selenium. 20

Cf. furthermore J. Dent.Res. Vol. 28 No. 2, page 160-171, 1949, wherein a wide range of tested compounds is mentioned.

Examples of active agents in the form of agents adjusting the pH in the oral cavity include for instance: acceptable acids, such as adipinic acid, succinic acid, fumaric acid, or salts thereof or salts of citric acid, tartaric acid, malic acid, acetic acid, lactic acid, phosphoric acid and glutaric acid and acceptable bases, such as carbonates, hydrogen carbonates, phosphates, sulfates or oxides of sodium, potassium, ammonium, magnesium or calcium, especially magnesium and calcium.

Examples of active agents in the form of anti-smoking agents include for instance: nicotine, tobacco powder or silver salts, for instance silver acetate, silver carbonate and silver nitrate.

In a further embodiment of the invention, the sucrose fatty acid esters may also be utilized for increased release of sweeteners including for instance the so-called highly potent sweeteners, such as for instance saccharin, cyclamate, aspartame, thaumatin, dihydrocalcones, stevioside, glycyrrhizin or salts or compounds thereof. For increased released of sweetener, the sucrose fatty acids preferably have a content of palmitate of at least 40% such as at least 50%.

Further examples of active agents are medicines of any type.

- Examples of active agents in the form of medicines include caffeine, salicylic acid, salicyl amide and related substances (acetylsalicylic acid, choline salicylate, mag-15 nesium salicylate, sodium salicylate), paracetamol, salts of pentazocine (pentazocine hydrochloride and pentazocinelactate), buprenorphine hydrochloride, codeine hydrochloride and codeine phosphate, morphine and morphine salts (hydrochloride, sulfate, tartrate), methadone hydrochloride, ketobemidone and salts of ketobemidone (hydrochloride), beta-blockers, (propranolol), calcium antagonists, verapamil 20 hydrochloride, nifedinpine as well as suitable substances and salts thereof mentioned in Pharm. Int., Nov.85, pages 267-271, Barney H. Hunter and Robert L. Talbert, nitroglycerine, erythrityl tetranitrate, strychnine and salts thereof, lidocaine, tetracaine hydrochloride, etorphine hydrochloride, atropine, insulin, enzymes (for instance papain, trypsin, amyloglucosidase. glucoseoxidase, streptokinase, 25 streptodomase, dextranase, alpha amylase), polypeptides (oxytocin, gonadorelin, (LH.RH), desmopressin acetate (DDAVP), isoxsuprine hydrochloride, ergotamine compounds, chloroquine (phosphate, sulfate), isosorbide, demoxytocin, heparin.
  - 30 Other active ingredients include beta-lupeol, Letigen<sup>®</sup>, Sildenafil citrate and derivatives thereof.

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base additives.

Dental products include Carbamide, CPP Caseine Phospho Peptide; Chlorhexidine, Chlorhexidine di acetate, Chlorhexidine Chloride, Chlorhexidine di gluconate, Hexetedine, Strontium chloride, Potassium Chloride, Sodium bicarbonate, Sodium carbonate, Fluor containing ingredients, Fluorides, Sodium fluoride, Aluminum fluoride, Ammonium fluoride, Calcium fluoride, Stannous fluoride, Other fluor containing ingredients Ammonium fluorosilicate, Potasium fluorosilicate, Sodium fluorosilicate, Ammonium monofluorphosphate, Calcium monofluorphosphate, Potassium monofluorphosphate, Sodium monofluorphosphate, Octadecentyl Ammonium fluoride, Stearyl Trihydroxyethyl Propylenediamine Dihydrofluoride, Vitamins include A, B1, B2, B6, B12, Folic acid, niacin, Pantothensyre, biotine, C, D, E, K. Minerals include Calcium, phosphor, magnesium, iron, Zink, Cupper, Iod, Mangan, Crom, Selene, Molybden. Other active ingredients include: Q10<sup>®</sup>, enzymes. Natural drugs including Ginkgo Biloba, ginger, and fish oil.

The invention also relates to use of migraine drugs such as Serotonin antagonists:

Sumatriptan, Zolmitriptan, Naratriptan, Rizatriptan, Eletriptan; nausea drugs such as

Cyclizin, Cinnarizin, Dimenhydramin, Difenhydrinat; hay fever drugs such as

Cetrizin, Loratidin, pain relief drugs such as Buprenorfin, Tramadol, oral disease

drugs such as Miconazol, Amphotericin B, Triamcinolonaceton; and the drugs

Cisaprid, Domperidon, Metoclopramid. In a preferred embodiment the invention

relates to the release of Nicotine and its salts.

The above-mentioned active ingredients and/or flavors may be pre-mixed into the gum base.

When the gum base granules comprise pre-mixed active ingredients, a controlled release of active ingredients may be obtained by means of at least a double active ingredients buffer, the first buffer comprising active ingredients blended into the final mix immediately prior to compression, the second buffer comprising active ingredients blended into the gum base prior to the blending of gum base and gum

Generally, release of flavor and/or active ingredients may be adjusted by adjustment of the balance between pre-mixed ingredients and the chewing gum additives added prior to compression.

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In step 24, the resulting blend is prepared for tableting by means of sieving.

The degree of sieving depends primarily of how the gum base granulate(s) "reacts" when chewing gum additives are blended together.

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If suitable, an initial pre-forming of the granulates are supplemented by spraying the barrier layer at the surface or at least a part of the surface of the pre-formed granulates. This technique and variants thereof may be referred to as an explicit barrier layer depositing.

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However, preferably, the barrier layer is established in a more implicit way. This technique and variants thereof may be referred to as implicit barrier layer depositing. This technique implies that the barrier layer compound is sprayed or deposited initially on the contacting surfaces of the pressing tools of a compression machine.

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An applicable technique suitable for implicit-barrier layer depositing is disclosed in US patent 5,643,630.

In step 25, the grinded blend is applied to the pressing tools of a tableting machine and compressed into chewing gum tablets.

The applied barrier layer may comprise of e.g. lubricants, anti-adherents and glidants.

30 Magnesium stearate may e.g. be applied as a pulverized parting compound.

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The barrier layer may be added to the final tablet for example by depositing dosed quantities of pulverized lubricants and parting compounds on the material contacting surfaces of pressing tools of tableting machines.

The barrier layer may be established by means of for example metallic stearates, hydrogenated vegetable oils, partially hydrogenated vegetable oils, polyethylene glycols, polyoxyethylene monostearates, animal fats, silicates, silicates dioxide, talc, magnesium stearates, calcium stearates, fumed silica, powdered hydrogenated cottonseed oils, hydrogenated vegetable oils, hydrogenated soya oil and mixtures thereof.

In step 26, which is optional, but preferred, the tableted chewing gum is provided with a suitable coating.

In accordance with an embodiment the invention, the chewing gum element comprises about 5% to about 98% by weight of the complete weight of the coated chewing gum. In the present context, a suitable outer coating is any coating that results in an extended storage stability of the compressed chewing gum products as defined above, relative to a chewing gum of the same composition that is not coated.

Thus, suitable coating types include hard coatings, film coatings and soft coatings of any composition including those currently used in coating of chewing gum, pharmaceutical products and confectioneries.

According to a preferred embodiment of the invention, film coating is applied to the compressed chewing gum tablet.

One presently preferred outer coating type is a hard coating, which term is used in the conventional meaning of that term including sugar coatings and sugar-free (or sugarless) coatings and combinations thereof. The objects of hard coating are to obtain a sweet, crunchy layer, which is appreciated by the consumer, and to protect the gum centers for various reasons. In a typical process of providing the chewing gum centers with a protective sugar coating the gum centers are successively treated

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in suitable coating equipment with aqueous solutions of crystallizable sugar such as sucrose or dextrose, which, depending on the stage of coating reached, may contain other functional ingredients, e.g. fillers, colors, etc. In the present context, the sugar coating may contain further functional or active compounds including flavor compounds, pharmaceutically active compounds and/or polymer degrading substances.

In the production of chewing gum it may, however, be preferred to replace the cariogenic sugar compounds in the coating by other, preferably crystallizable, sweetening compounds that do not have a cariogenic effect. In the art such coating is generally referred to as sugarless or sugar-free coatings. Presently preferred non-cariogenic hard coating substances include polyols, e.g. sorbitol, maltitol, mannitol, xylitol, erythritol, lactitol, isomalt and tagatose which are obtained by industrial methods by hydrogenation of D-glucose, maltose, fructose or levulose, xylose, erythrose, lactose, isomaltulose and D-galactose, respectively.

In a typical hard coating process, as it will be described in details in the following, a syrup containing crystallizable sugar and/or polyol is applied onto the gum centers and the water it contains is evaporated off by blowing with warm, dry air. This cycle must be repeated several times, typically 10 to 80 times, in order to reach the swelling required. The term "swelling" refers to the increase in weight of the products, as considered at the end of the coating operation by comparison with the beginning, and in relation to the final weight of the coated products. In accordance with the present invention, the coating layer constitutes about 1 to about 75% by weight of the finished chewing gum element, such as about 10 to about 60% by weight, including about 15 to about 50% by weight.

In further useful embodiments of the invention, the outer coating of the chewing gum element is an element that is subjected to a film coating process and which therefore comprises one or more film-forming polymeric agents and optionally one or more auxiliary compounds, e.g. plasticizers, pigments and opacifiers. A film coating is a thin polymer-based coating applied to a chewing gum center of any of the above

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forms. The thickness of such a coating is usually between 20 and 100 µm. Generally, the film coating is obtained by passing the chewing gum centers through a spray zone with atomized droplets of the coating materials in a suitable aqueous or organic solvent vehicle, after which the material adhering to the gum centers is dried before the next portion of coating is received. This cycle is repeated until the coating is complete.

In the present context, suitable film-coating polymers include edible cellulose derivatives such as cellulose ethers including methylcellulose (MC), hydroxyethyl cellulose (HEC), hydroxypropyl cellulose (HPC) and hydroxypropyl methylcellulose (HPMC). Other useful film-coating agents are acrylic polymers and copolymers, e.g. methylacrylate aminoester copolymer or mixtures of cellulose derivatives and acrylic polymers. A particular group of film-coating polymers also referred to, as functional polymers are polymers that, in addition to its film-forming characteristics, confer a modified release performance with respect to active components of the chewing gum formulation. Such release modifying polymers include methylacrylate ester copolymers, ethylcellulose (EC) and enteric polymers designed to resist the acidic stomach environment, yet dissolve readily in the duodenum. The latter group of polymers includes: cellulose acetate phtalate (CAP), polyvinyl acetate phtalate (PVAP), shellac, metacrylic acid copolymers, cellulose acetate trimellitate (CAT) and HPMC. It will be appreciated that the outer film coating according to the present invention may comprise any combination of the above film-coating polymers.

In other embodiments of the invention, the film-coating layer of the chewing gum elements comprise a plasticizing agent having the capacity to alter the physical properties of a polymer to render it more useful in performing its function as a film-forming material. In general, the effect of plasticizers will be to make the polymer softer and more pliable as the plasticizer molecules interpose themselves between the individual polymer strands thus breaking down polymer-polymer interactions. Most plasticizers used in film coating are either amorphous or have very little crystallinity. In the present context, suitable plasticizers include polyols such as glycerol, propylene glycol, polyethylene glycol, e.g. the 200-6000 grades hereof, organic

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esters such as phtalate esters, dibutyl sebacate, citrate esters and thiacetin, oils/glycerides including castor oil, acetylated monoglycerides and fractionated coconut oil.

- The choice of film-forming polymer(s) and plasticizing agent(s) for the outer coating of the present chewing gum element is made with due consideration for achieving the best possible barrier properties of the coating in respect of dissolution and diffusion across the film of moisture and gasses.
- The film coating of the chewing gum elements may also contain one or more colorants or opacifiers. In addition to providing a desired color hue, such agents may contribute to protecting the compressed gum base against pre-chewing reactions, in particular by forming a barrier against moisture and gasses. Suitable colorants/pacifiers include organic dyes and their lakes, inorganic coloring agents, e.g.
   titanium oxide and natural colors such as e.g. β-carotene.

Additionally, film coatings may contain one or several auxiliary substances such as flavors and waxes or saccharide compounds such as polydextrose, dextrins including maltodextrin, lactose, modified starch, a protein such as gelatine or zein, a vegetable gum and any combination thereof.

It is also an aspect of the present invention that the outer coating of the chewing gum element can contain one or more pharmaceutically or cosmetically components including those mentioned hereinbefore.

Accordingly, in further embodiments of the invention, the above hard-coated or film-coated chewing gum element is an element where the outer coating comprises at least one additive component selected from a binding agent, a moisture absorbing component, a film forming agent, a dispersing agent, an anti-sticking component, a bulking agent, a flavoring agent, a coloring agent, a pharmaceutically or cosmetically active component, a lipid component, a wax component, a sugar and an acid. If it is desired to defer the effect of any of these additive components in the outer coating

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until mastication of the chewing gum, such components may, in accordance with the invention be encapsulated using any conventional encapsulation agent such as e.g. a protein including gelatine and soy protein, a cellulose derivative including any of those mentioned above, a starch derivative, edible synthetic polymers and lipid substances, the latter optionally in the form of liposome encapsulation.

In other embodiments of the invention, the chewing gum element is provided with an outer coating in the form generally described in the art as a soft coating. Such soft coatings are applied using conventional methods and may advantageously consist of a mixture of a sugar or any of the above non-cariogenic, sugar-less sweetening compounds, and a starch hydrolysate.

Again, it should be noted that the above-described coating is optional or that it may be postponed until it fits into the last part of the manufacturing process due to the fact that the applied barrier layer is also acting as a complete or at least a partial barrier to transfer of humidity from the environment into the tablet.

Fig. 2b illustrates a further embodiment of the invention.

Basically, the illustrated process corresponds to the process illustrated in fig. 2a, although some important process steps have been modified, namely step 21 and the omission of step 22.

When applying a high-speed mixing process, e.g. by means of a Lipp-mixer, granules of relatively small size may be obtained, thereby facilitating the possibility of omitting the step of milling in step 22. Evidently, such omission of a process step requires a relatively high quality of the output product of the high-speed mixer in step 21, and different quality measures may be established.

An alternative and very advantageous method of preparing a resin-comprising chewing gum, i.e. by means of so-called premixing of flavors into the gum base polymers, is described in PCT/DK02/00462, hereby incorporated by reference.

Fig. 3a to fig. 3e illustrate some important features of one embodiment of the invention.

5 The figures 3a to 3e illustrate a possible application of the already described 25 of fig. 2.

The below-described barrier depositing method has been referred to as implicit barrier layer depositing. As mentioned above, this technique implies that the barrier layer compound is sprayed or deposited initially on the contacting surfaces of the pressing tools of a compression machine. An applicable technique suitable for implicit-barrier layer depositing is disclosed in US patent 5,643,630.

In fig. 3a a first part of a pressing tool 31 has been provided.

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In fig. 3b, dosed quantities of pulverized lubricants of parting compounds have been deposited on the first part 31 of the pressing tool. The deposited layer L1 constitutes a first part of the final barrier layer of the final chewing gum.

- In fig. 3c, a blend, as provided in step 23 and 24, is injected into the pressing tool 31.

  The blend comprises gum base granules 32 and gum base additives 33 such as additional sweeteners, additional flavors, etc. Suitable chewing gum additives have been disclosed above.
- In fig. 3d, a second part of a pressing tool 35 has been provided with a second part of the final barrier layer L2.

In fig. 3e, the pressing tools 31 and 35 has been pressed together, thereby invoking a compression of the gum base blending of gum base granules 32 and further chewing gum additives 33. Basically, the resulting chewing gum tablet 37 comprises a chewing gum center 38 comprising a compression of the gum base granules 32 and the gum base additives 33.

A final barrier layer 39 is formed as a combining of barrier layer L1 and barrier layer L2.

According to the invention, the - evidently moderated - tackiness of the gum base granules 32 or at least a part of the granules is provided by means of e.g. natural resins incorporated in the gum base granulate.

Fig. 4a to 4d illustrate a further embodiment of the invention.

In fig. 4a a first part of a pressing tool 41 has been provided.

In fig. 4b, a blend, e.g. as provided according to the processes illustrated in fig. 2a and 2b is injected into the pressing tool 41. The blend comprises gum base granules 42 and gum base additives 43 such as additional sweeteners, additional flavors, etc. Suitable chewing gum additives have been disclosed above.

In fig. 4c, a second part of a pressing tool 45 has been provided.

In fig. 4d, the pressing tools 41 and 45 have been pressed together, thereby invoking a compression of the gum base blending of gum base granules 42 and further chewing gum additives 43. Basically, the resulting chewing gum tablet 47 comprises a chewing gum center 48 comprising a compression of the gum base granules 42 and the gum base additives 43.

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The final tablets of e.g. fig. 3e and 4d may moreover be provided with a coating.

Compared to conventionally mixed chewing gum, the compression of a gum base granulate together with chewing gum additives is a relatively lenient gathering of the final chewing gum, at least with respect to temperature. However, the omission of the thoroughly tearing of the granulate together with the desired additives will,

according to conventional chewing gum, result in a risk of crumbling and disintegration especially during the initial chew.

According to the invention, the provided chewing gum featuring tacky granules may counteract the initial-chew invoked disintegration to such a degree that the chewing gum remains non-crumbling until the granules are finally mixed during the chewing of the chewing gum.

Three different examples of compressed chewing gum were prepared according to the invention according to the process of fig. 2a. One example was prepared completely without natural resin.

The below numbers refer to% by weight of the complete final chewing gum. The provided chewing gums were not provided with an added coating.

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	ex.1	ex.2	ex.3	ex.4
Gum base	37	32	35	32
Sorbitol	58	61	60	61
Flavor	4	7	5	7
APM	0.15	0.15	0.15	0.15
ACK	0.15	0.15	0.15	0.15
(nat. resin)	(5.1)	(2.0)	(4)	(-)

The last row refers to the amount of natural resin of the complete chewing gum.

The provided chewing gum was tested by a sensory panel of 8 persons.

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Example 1 and 3 were deemed to have an impressing initial chew and moreover an impressing flavor release. Deemed OK.

Example 2 was deemed to be OK, but giving a feeling of a little more vulnerable initial chew.

Example 4 had an almost liquid consistence, and the obtained chewing gum was deemed not OK.

5 Further examples of embodiments of the invention will be described below.

Example 5
Preparation of gum bases

The gum bases were composed as described in the following table:

Raw Material	GB-1	GB-2	GB-3	GB-4	GB-5
Elastomer	6.5	14.0	24.0	16.5	17.5
Natural resin	20.0	0.0	0.0	10.0	5.0
PVA	23.0	30.0	40.0	27.8	27.8
Filler	27.0	28.0	0.0	20.3	24.3
Emulsifier	9.0	9.0	11.0	8.0	8.0
Fat	0.0	19.0	25.0	17.4	17.4
Wax	14.5	0.0	0.0	0.0	0.0

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The gum bases are prepared as follows:

The elastomers are added to a mixing kettle provided with mixing means like e.g. horizontally placed Z-shaped arms. The elastomers are broken into small pieces and softened with mechanical action on the kettle.

The natural resins are slowly added to the elastomers and when the mixture becomes homogeneous the PVA is added. During the phase of mixing the elastomers with the natural resins and the PVA the filler is admixed successively in portions capable of being absorbed into the mixture. The softening system comprising emulsifiers, fats and/or wax is slowly added into the mixture and mixing is continued until a homogenous gum base is obtained. Mixing time is typically in the range of 30 minutes to 4 hours depending of the composition and mixing technology. The mixing temperature will typically be in the range from 50° C to 120° C.

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The mixture is then discharged into the pan or pelletizied and allowed to cool to room temperature from the discharged temperature of 50-120° C.

5 The compressed chewing gum formulation is as follows.

Raw Material	Ingredient (%)	
Gum Base	35	
Sorbitol	60	
Flavor	5	
APM	0.15	
ACK	015	

The resulting compressed chewing gums prepared according to the process of fig. 2b were evaluated both with respect to texture properties in a sensory test and with respect to the high-speed mixing performance:

Gum Base	Sensory evaluation	High-speed mixing	
formulation		performance	
GB-1	Excellent	Acceptable	
GB-2	Not acceptable	Excellent	
GB-3	Not acceptable	Excellent	
GB-4	Good	Acceptable	
GB-5	Acceptable	Good	

The sensory evaluation of the texture was made with reference to a conventional chewing gum, which is ranked, as excellent. And the high-speed mixing performance was made with reference to whether the granules obtained from the high-speed mixer did not need subsequently milling before entering the compression process which was ranked as excellent.

Mixtures exceeding 50% of natural resins were not acceptable for the high-speed mixer due to sticking and lumps creation during the process.

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## **Patent Claims**

- 1. Gum base granules comprising
- -at least one elastomer in an amount of about 3% to about 35% by weight of the gum base,
- -at least two resins in an amount of about 15% to about 60% by weight of the gum base,
  - -gum base ingredients, and where

said at least two resins comprising

- -natural resin in an amount of about 5% to about 40% by weight of the gum base
  - -synthetic resin in an amount of about 10% to about 40% by weight of the gum base
- 2. Gum base granules according to claim 1,wherein said natural resin comprises one or more different natural resins.
  - 3. Gum base granules according to claim 1 or 2, wherein said synthetic resin comprises one or more different synthetic resins.
  - 4. Gum base granules according to any of the claims 1-3, wherein the ratio between the synthetic resin and the natural resin is from about 0.5 to about 7, preferably from about 0.9 to about 6.0.
- 5. Gum base granules according to any of the claims 1-4, wherein the ratio between the synthetic resin and the natural resin is from about 0.9 to about 2.0, preferably from about 0.9 to about 1.5.
  - 6. Gum base granules according to any of the claims 1-5,
- 30 wherein said natural resin comprises rosin esters.
  - 7. Gum base granules according to any of the claims 1-6,

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wherein said natural resin comprises terpene resins, e.g. derived from alpha-pinene, beta-pinene, and/or d-limonene, natural terpene resins, glycerol esters of gum rosins, tall oil rosins, wood rosins or other derivatives thereof such as glycerol esters of partially hydrogenated rosins, glycerol esters of polymerized rosins, glycerol esters of partially dimerised rosins, pentaerythritol esters of partially hydrogenated rosins, methyl esters of rosins, partially hydrogenated methyl esters of rosins or pentaerythritol esters of rosins and combinations thereof.

- 8. Gum base granules according to any of the claims 1-7,
- wherein said synthetic resin comprises polyvinyl acetate, vinyl acetate-vinyl laurate copolymers and mixtures thereof.
- 9. Gum base granules according to any of the claims 1-8,
  wherein said granulated gum base comprising at least one high molecular weight
  elastomer in an amount of about 0% to about 15% by weight of said gum base.
  - 10. Gum base granules according to any of the claims 1-9, wherein the molecular weight of said at least one high molecular weight elastomer is from about 50000 g/mol to 800000 g/mol Mn.
  - 11. Gum base granules according to any of the claims 1-10, wherein said granulated gum base comprising at least one low molecular weight elastomer is in an amount of about 0% to about 25% by weight of said gum base.
- 25 12. Gum base granules according to any of the claims 1-11, wherein the molecular weight of said at least one low molecular weight elastomer is from about 1000 g/mol to 50000 g/mol Mn.
  - 13. Gum base granules according to any of the claims 1-12, wherein said gum base is added lubricants, anti-adherents and glidants such as metallic stearates, hydrogenated vegetable oils, partially hydrogenated vegetable oils, polyethylene glycols, polyoxyethylene monostearates, animal fats, silicates, silicates

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dioxide, talc, magnesium stearates, calcium stearates, fumed silica, powdered hydrogenated cottonseed oils, hydrogenated vegetable oils, hydrogenated soya oil and mixtures thereof.

- 5 14. Gum base granules according to any of the claims 1-13, wherein the gum base is substantially free of lubricants, anti-adherents and glidants.
- 15. Gum base granules according to any of the claims 1-14,
  wherein the natural resins provides an improved and sticky texture of the gum base
  when applied in chewing gum formulation.
  - 16. Gum base granules according to any of the claims 1-15, wherein said gum base is substantially wax free.
- 15 17. Gum base granules according to any of the claims 1-15, wherein said gum base is substantially fat free.
- 18. Gum base granules according to any of the claims 1-17, wherein the gum base has a water content of less than 2.0%, preferably less than 2.0 1.5% by weight of the gum base.
  - 19. Gum base granules according to any of the claims 1-18, wherein said gum base comprises filler in an amount of about 0% to about 50% by weight of the gum base.
  - 20. Gum base granules according to any of the claims 1-19, wherein said gum base granules comprises active ingredients, at least a part of said active ingredients been teared into the chewing gum forming granules or at least a part of the chewing gum forming granules previous to compression..
  - 21. Gum base granules according to any of the claims 1-20,

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wherein said gum base comprises synthetic resin in an amount of about 15% to about 40% by weight of the gum base.

- 22. Gum base granules according to any of the claims 1-21,
- 5 wherein said gum base comprises emulsifiers and/or fats in an amount of about 10% to about 40% by weight of the gum base.
  - 23. Gum base granules according to any of the claims 1-22, wherein said gum base comprises wax in an amount of about 2% to about 30% by weight of the gum base.
  - 24. Gum base granules according to any of the claims 1-23, wherein at least a part of the flavoring agents has been teared into the gum base or at least a part of the gum base previous to compression.

25. Compressed chewing gum comprising

elastomer in the amount of about 0% to 32% by weight, preferably about 5% to 25% by weight of the chewing gum,

resin in the amount of about 1.5% to 55% by weight, preferably about 4% to 30% by weight of the chewing gum

and chewing gum additives,

- 25 wherein said resin comprises
  - -natural resin in the amount of about 0.5% to 35% by weight, preferably about 4% to 30% by weight of the chewing gum,
- -synthetic resin in the amount of about 1% to 35% by weight, preferably about 4% to 30% by weight of the chewing gum,
  - 26. Compressed chewing gum according to claim 25,

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wherein said chewing gum additives comprise sweeteners in the amount of about 5 to about 95% by weight of the chewing gum, more typically about 20 to about 80% by weight such as 30 to 60% by weight of the chewing gum.

- 5 27. Compressed chewing gum according to claim 25 or 26, wherein the compressed chewing gum tablet comprises about 0.1% to 15% by weight of flavoring agents, preferably about 0.8% to 5% by weight
- 28. Compressed chewing gum according to any of the claims 25-27,wherein said natural resin comprises one or more different natural resins.
  - 29. Compressed chewing gum according to any of the claims 25-28, wherein said synthetic resin comprises one or more different synthetic resins.
- 30. Compressed chewing gum according to any of the claims 25-29, wherein the ratio between the synthetic resin and the natural resin is from about 0.5 to about 7, preferably from about 0.9 to about 6.0.
- 31. Compressed chewing gum according to any of the claims 25-30,
  wherein the ratio between the synthetic resin and the natural resin is from about 0.9 to about 2.0, preferably from about 0.9 to about 1.5.
  - 32. Compressed chewing gum according to any of the claims 25-31, wherein said natural resin comprises rosin esters
  - 33. Compressed chewing gum according to any of the claims 25-32, wherein said natural resin comprises terpene resins, e.g. derived from alpha-pinene, beta-pinene, and/or d-limonene, natural terpene resins, glycerol esters of gum rosins, tall oil rosins, wood rosins or other derivatives thereof such as glycerol esters of partially hydrogenated rosins, glycerol esters of polymerized rosins, glycerol esters of partially dimerised rosins, pentaerythritol esters of partially hydrogenated rosins,

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methyl esters of rosins, partially hydrogenated methyl esters of rosins or pentaerythritol esters of rosins and combinations thereof.

- 34. Compressed chewing gum according to any of the claims 25-33,
- 5 wherein said synthetic resin comprises polyvinyl acetate, vinyl acetate-vinyl laurate copolymers and mixtures thereof-
  - 35. Compressed chewing gum according to any of the claims 25-34, wherein said chewing gum comprising at least one high molecular weight elastomer in an amount of about 0.5% to about 14% by weight of said chewing gum.
    - 36. Compressed chewing gum according to any of the claims 25-35, wherein the molecular weight of said at least one high molecular weight elastomer is from about 50000 g/mol to 800000 g/mol Mn.
- 37. Compressed chewing gum according to any of the claims 25-36, wherein said chewing gum comprising at least one low molecular weight elastomer is in an amount of about 0% to about 20% by weight of said chewing gum.
- 38. Compressed chewing gum according to any of the claims 25-37, wherein the molecular weight of said at least one low molecular weight elastomer is from about 1000 g/mol to 50000 g/mol Mn.
  - 39. Compressed chewing gum according to any of the claims 25-38.
- wherein said chewing gum comprises lubricants, anti-adherents and glidants such as metallic stearates, hydrogenated vegetable oils, partially hydrogenated vegetable oils, polyethylene glycols, polyoxyethylene monostearates, animal fats, silicates, silicates dioxide, talc, magnesium stearates, calcium stearates, fumed silica, powdered hydrogenated cottonseed oils, hydrogenated vegetable oils, hydrogenated soya oil and mixtures thereof.
  - 40. Compressed chewing gum according to any of the claims 25-39,



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wherein the chewing gum is substantially free of lubricants, anti-adherents and glidants.

- 41. Compressed chewing gum according to any of the claims 25-40, wherein the natural resins provide an improved and sticky texture of the chewing gum when applied in chewing gum formulation.
- 42. Compressed chewing gum according to any of the claims 25-41, wherein said chewing gum is substantially wax free.

43. Compressed chewing gum according to any of the claims 25-41, wherein said chewing gum is substantially fat free.

- 44. Compressed chewing gum according to any of the claims 25-43,
  wherein the chewing gum has a water content of less than 2.0%, preferably less than 1.5% by weight of the chewing gum.
- 45. Compressed chewing gum according to any of the claims 25-44,
  wherein said chewing gum comprises filler in an amount of about 0% to about 50%
  by weight of the chewing gum.
  - 46. Compressed chewing gum according to any of the claims 25-45, wherein said chewing gum comprises synthetic resin in an amount of about 1.5% to about 35% by weight of the chewing gum.
  - 47. Compressed chewing gum according to any of the claims 25-46, wherein said chewing gum comprises emulsifiers and/or fats in an amount of about 1% to about 45% by weight of the chewing gum.
- 30 48. Compressed chewing gum according to any of the claims 25-47, wherein said chewing gum comprises wax in an amount of about 0.5 to about 30% by weight of the chewing gum.





- 49. Compressed chewing gum according to any of the claims 25-48, wherein at least a part of the flavoring agents have been teared into the chewing gum forming granules or at least a part of the chewing gum forming granules previous to compression.
  - 50. Compressed chewing gum according to any of the claims 25-49, wherein said chewing gum additives comprise active ingredients.
- 51. Compressed chewing gum according to any of the claims 25-50, wherein at least a part of said active ingredients has been teared into the chewing gum forming granules or at least a part of the chewing gum forming granules previous to compression.
- 52. Compressed chewing gum comprising gum base according to any of the claims 1-24 in an amount of about 10% to 90% by weight of the chewing gum tablet.
  - 53. Compressed chewing gum according to any of the claims 25-52, wherein the chewing gum has been coated.

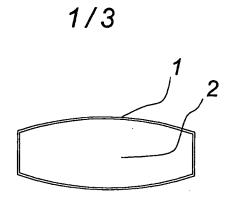


Fig.1

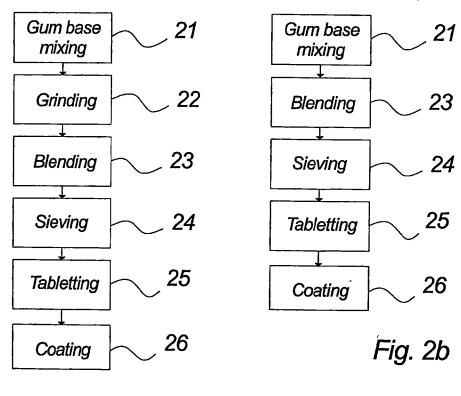
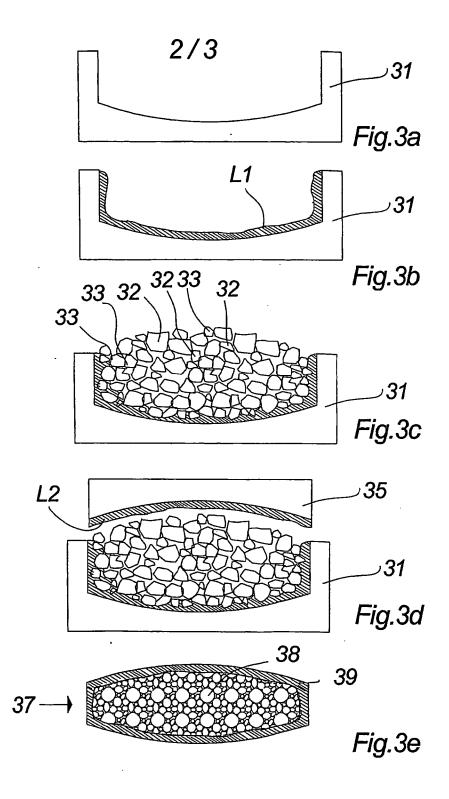
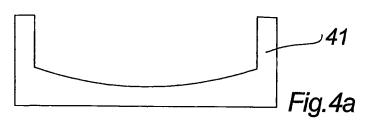
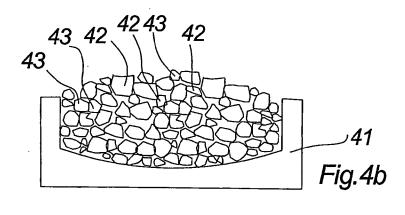


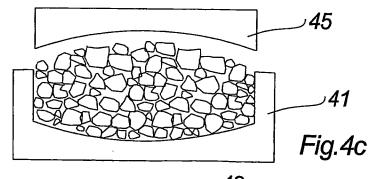
Fig. 2a



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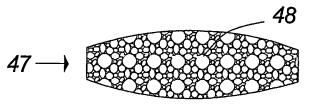


Fig.4d



## INTERNATIONAL SEARCH REPORT

polication No

PCT/DK 03/00465 A CLASSIFICATION OF SUBJECT MATTER IPC 7 A2363/30 According to International Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) A236 IPC 7 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practical, search terms used) EPO-Internal, WPI Data, PAJ, FSTA C. DOCUMENTS CONSIDERED TO BE RELEVANT Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No. 1-53 US 6 322 806 B1 (CORRIVEAU CHRISTINE L ET X AL) 27 November 2001 (2001-11-27) column 6-13; claims; examples 1-53 WO 02 071860 A (ZUROMSKI EDWARD J ;LI P.X WEISHENG (US); HARTMAN SCOTT E (US); KANCA K) 19 September 2002 (2002-09-19) the whole document 1 - 24WO 01 72139 A (WRIGLEY W M JUN CO) X 4 October 2001 (2001-10-04) page 4-13; claims; examples US 4 753 805 A (BIKKINA KIRSHNAYYA ET AL) 1-53 X 28 June 1988 (1988-06-28) column 6; claims; examples -/--Further documents are listed in the continuation of box C. Patent family members are listed in annex. Special categories of cited documents : T later document published after the International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the "A" document defining the general state of the art which is not considered to be of particular relevance invention "E" earlier document but published on or after the International "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another cliation or other special reason (as specified) "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such document. "O" document referring to an oral disclosure, use, exhibition or ments, such combination being obvious to a person skilled in the art. \*P\* document published prior to the international filing date but later than the priority date claimed "&" document member of the same patent family Date of the actual completion of the international search Date of mailing of the international search report

20/10/2003

Boddaert, P

Authorized officer

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PCT/DK 03/00465

		PC1/DK 03/00465
C.(Continua	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	Relevant to claim No.
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Helevant to claim No.
X	US 6 200 608 B1 (ZUROMSKI EDWARD J ET AL) 13 March 2001 (2001-03-13) column 3-8; claims; examples	1-24
P,X	WO 02 051258 A (ATP AVANT GARDE TECHNOLOGIES P ;BADETTI ROLANDO (IT)) 4 July 2002 (2002-07-04) the whole document	1–53
P,X	WO 02 078459 A (PRODUITS NESTLES S A SOC D; SOLDANI CRISTIANA (IT)) 10 October 2002 (2002-10-10) the whole document	1-53
X	US 2001/002998 A1 (CORRIVEAU CHRISTINE L ET AL) 7 June 2001 (2001-06-07) the whole document	1-53
Ρ,Χ	WO 02 069729 A (ZUROMSKI EDWARD J ;LI WEISHENG (US); HARTMAN SCOTT E (US); KANCA K) 12 September 2002 (2002-09-12) the whole document	1-53
х	US 5 536 511 A (YATKA ROBERT J) 16 July 1996 (1996-07-16) column 3, line 65 -column 6, line 67	1-53
X	EP 0 221 850 A (WARNER LAMBERT CO) 13 May 1987 (1987-05-13) the whole document	1-53
A	SECTZER J.: "Chewing gums embrace good for you profile" CANDY INDUSTRY, vol. 166, no. 9, 2001, page 36-40 XP008023005 page 38 page 40	1-53
A	DE 28 08 160 A (NORDSTROEM RABBE) 30 August 1979 (1979-08-30)	
A	US 5 866 179 A (TESTA EMILIO STEFANO) 2 February 1999 (1999-02-02)	
A	US 5 087 459 A (CHUU MICHAEL S ET AL) 11 February 1992 (1992-02-11)	



PCT/DK 03/00465

Information on patent family members

Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 6322806	B1	27-11-2001	US CA WO US US AU BR CA CN EP JP PL	6355265 B1 2426349 A1 03030875 A1 2003003152 A1 2001002998 A1 6426090 B1 4032700 A 0009604 A 2365826 A1 1346283 T 1173215 A1 2002541123 T 350656 A1	12-03-2002 17-04-2003 17-04-2003 02-01-2003 07-06-2001 30-07-2002 23-10-2000 26-12-2001 12-10-2000 24-04-2002 23-01-2002 03-12-2002 27-01-2003
			WO US US US US US AU BR	0059543 A1 2002110581 A1 2001024642 A1 2002039560 A1 2002159956 A1 2003049208 A1 2184300 A 9916303 A	12-10-2000 15-08-2002 27-09-2001 04-04-2002 31-10-2002 13-03-2003 03-07-2000 02-10-2001
			CA EP US US US US	2355779 A1 1139774 A1 2002164398 A1 6627234 B1 2001021373 A1 2002012633 A1 4030800 A 2369515 A1	22-06-2000 10-10-2001 07-11-2002 30-09-2003 13-09-2001 31-01-2002 24-04-2001 29-03-2001
			CA CN EP JP WO US	1330516 T 1181010 A1 1221863 A1 2003509455 T 0121156 A1 6531114 B1	09-01-2002 27-02-2002 17-07-2002 11-03-2003 29-03-2001 11-03-2003
WO 02071860	Α	19-09-2002	MO	02071860 A1	19-09-2002
WO 0172139	A	04-10-2001	WO AU US	0172139 A1 3915800 A 6200608 B1	04-10-2001 08-10-2001 13-03-2001
US 4753805	A	28-06-1988	AU CA EP ES JP ZA	3668684 A 1240875 A1 0151344 A2 8608288 A1 60164438 A 8409689 A	08-08-1985 23-08-1988 14-08-1985 01-12-1986 27-08-1985 31-07-1985
US 6200608	B1	13-03-2001	WO AU	0172139 A1 3915800 A	04-10-2001 08-10-2001
WO 02051258	A	04-07-2002	IT WO	MI20002810 A1 02051258 A2	24-06-2002 04-07-2002
WO 02078459	Α	10-10-2002	WÓ	02078459 A1	10-10-2002
US 2001002998	A1	07-06-2001	US	6322806 B1	27-11-2001



Information on patent family members

				PC1/D	( 03/00405
Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 2001002998	A1		US	6355265 B1	12-03-2002.
00 2001002330			CA	2426349 A1	17-04-2003
			WO	03030875 A1	17-04-2003
			ÜS	2003003152 A1	02-01-2003
			US	6426090 B1	30-07-2002
			AU	4032700 A	23-10-2000
			BR	0009604 A	26-12-2001
			CA	2365826 A1	12-10-2000
			CN	1346283 T	24-04-2002
			EP	1173215 A1	23-01-2002
			JP	2002541123 T	03-12-2002
			PL	350656 A1	27-01-2003
			MO	0059543 A1	12-10-2000
			US	2002110581 A1	15-08-2002
			us	2001024642 A1	27-09-2001
			UŞ	2002039560 A1	04-04-2002
			US	2002159956 A1	31-10-2002
			US	2003049208 A1	13-03-2003
			ΑU	2184300 A	03-07-2000
			ΑU	4030800 A	24-04-2001
			BR	9916303 A	02-10-2001
			CA	2355779 A1	22-06-2000
			CA	2369515 A1	29-03-2001
			CN	1330516 T	09-01-2002
			EP	1181010 A1	27-02-2002
			ΕP	1139774 A1	10-10-2001
			ΕP	1221863 A1	17-07-2002
			ĴΡ	2003509455 T	11-03-2003
			WO	0121156 A1	29-03-2001
			ÜS	2002164398 A1	07-11-2002
			US	6627234 B1	30-09-2003
			บร	6531114 B1	11-03-2003
			US	2002012633 A1	31-01-2002
			US	2001021373 A1	13-09-2001
WO 02069729	A	12-09-2002	WO	02069729 A1	12-09-2002
US 5536511	A	16-07-1996	AU	680316 B2	24-07-1997
			ΑU	8070894 A	03-04-1995
			CA	2170498 A1	23-03-1995
			DE	69431261 D1	02-10-2002
			DE	69431261 T2	17-04-2003
			DK	785724 T3	06-01-2003
			EP	0785724 A1	30-07-1997
			ĴΡ	9502615 T	18-03-1997
			WO	9507625 A1	23-03-1995
			US	5603970 A	18-02-1997
		40 OF 100			
EP 0221850	Α	13-05-1987	AU	593589 B2	15-02-1990
			AU	6462186 A	07-05-1987
			DE	3672451 D1	09-08-1990
			EP	0221850 A2	13-05-1987
			GR	3000825 T3	15-11-1991
			JP	62179349 A	06-08-1987
			PT	83652 A ,B	
			, ,	0000= ,-	
			ZA	8607327 A	27-05-1987





information on patent family members

Internat pplication No
PCT/DK 03/00465

Patent document cited in search report	Publication date		Patent family member(s)	Publication date
US 5866179 A	02-02-1999	AT	200024 T	15-04-2001
		CA	2196150 A1	04-11-1997
1		DE	69704426 D1	03-05-2001
Ì		DE	69704426 T2	15-11-2001
1		DK	909166 T3	13-08-2001
l .		EP	0909166 A2	21-04-1999
<b>,</b>		ES	2157566 T3	16-08-2001
		GR	3036117 T3	28-09-2001
ì		MO	9741843 A2	13-11-1997
		JP	2001506227 T	15-05-2001
		PT	909166 T	28-09-2001
US 5087459 A	11-02-1992	AT	101006 T	15-02-1994
		AU	627412 B2	20-08-1992
		ΑU	6379990 A	11-04-1991
Į.		CA	2025741 A1	05-04-1991
		CN	1050671 A	17-04-1991
		DE	69006444 D1	17-03-1994
		DE	69006444 T2	23-06-1994
1		DE	421670 T1	28-11-1991
		DK	421670 T3	07-03-1994
}		EP	0421670 A2	10-04-1991
		ES	2048978 T3	01-04-1994